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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,397	08/02/2001	Pierre Legrain	EGYPSA-013	6024
530	7590	06/29/2004	EXAMINER	
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			MOSHER, MARY	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/921,397

Applicant(s)

LEGRAIN ET AL.

Examiner

Mary E. Mosher, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/8/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) 7-11, 22, 23, 25-61 and 63-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-19 is/are rejected.
- 7) ☒ Claim(s) 1-6, 12-16, 20, 21, 24 and 62 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Claims 7-11, 22, 23, 25, 27-61, 63-73 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group and/or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11 and 13. Claim 26 is also now withdrawn from consideration, as applicant's response indicates that the claim actually is meant to be drawn to a protein, not to a nucleic acid like parent claim 24. Claims 1-6, 12-21, 24, and 62 have been examined to the extent that they read upon SEQ ID NO: 58 or a sequence encoding SEQ ID NO: 20.

This application contains claims 1-73 drawn in whole or in part to an invention nonelected with traverse in the reply filed on 2/19/2003 and 6/11/2003. A complete reply to the final rejection must include cancellation of nonelected subject matter or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. **Withdrawn process claims that are not**

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commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Response to Amendment

In the amendment to Table 1 (pages 78-79), the directions say to delete "the five lines of commentary underneath..." This is confusing, because if only five lines are deleted, then the commentary becomes (1) (2) (3) (3) (4) (5). If all 5 comments are deleted, then there is no explanation of the (4) and (5) symbols in the Table. Also, in the line dealing with sequences 20 and 58, there appears to be a typo adding an extra digit to the number in the third column. To clarify the intended text, it is strongly suggested that applicant replace pages 78 and 79 in their entirety.

Claim Objections

Claims 17-19 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 17-19 recite "The recombinant vector of any one of claims 12 to 16, which is [list of named vectors]." The vectors which are pACTIIst, pAS2ΔΔ, pT25, pKT25, pUT18, pUT18C, P6 and pB5 do not contain any inserts. The parent claims 12-16 require inserts. Therefore, claims 17-19 are drawn to subject matter outside the scope of parent claims 12-16. This

objection could be obviated by restoring claims 12-16 to the original language, and rewriting claims 17-19 in the format: "The recombinant vector of any one of claims 12 to 16, which is wherein the nucleic acid is inserted in pT25, pKT25...."

Claim 24 is objected to because of the following informalities: "two nucleic acid" should be plural. Appropriate correction is required.

Claims 1-6, 12-21, 24, and 62 are objected to because the claims include nonelected inventions.

Claim Rejections - 35 USC § 112

Claims 17-19 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for reasons. Applicants argue that deposit of the specifically recited plasmids is not necessary, asserting that all of the plasmids (or the plasmids from which they were derived) were known in the prior art. However, the specification does not in any way point to the prior art which allegedly teaches one how to make the plasmids pAS2 $\Delta\Delta$, pACT11st, or the starting material used for making pP6, and the record does not establish that the disclosure in the prior art is sufficient to render the plasmids both known and readily available to the public. The specification does not provide any information about how to make plasmids pT25, pKT25, or pUT18C, and reference to figures 5-7 does not indicate the extent of differences from the plasmids they were "derived from." For pB5, specification page 68 does not identify pAS2 $\Delta\Delta$ as the starting material. However, on reconsideration, the requirement for deposit of pUT18 is withdrawn, in view of the commercial availability of this plasmid and the evidence that the full sequence of the plasmid was known in the prior art. However,

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for the rest of the plasmids recited in these claims, the requirement for deposit is maintained.

The rejection of claims 1-6, 12-21, 24, 26, and 62 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, is withdrawn in view of applicant's arguments.

Claim Rejections - 35 USC § 103

The rejection of claims 1-6, 12-16, 20, 21, 24, and 26 under 35 U.S.C. 102(b) as being anticipated by Yanagi et al (PNAS 94:8738-8743, 1997), is withdrawn in view of the amendment of claims 2 and 5 and applicant's arguments.

Allowable Subject Matter

Claims 1-6, 12-16, 20, 21, 24, and 62 would be allowable if limited to the elected invention. If limited to the scope of the elected nucleic acid, method claims 27-30 could be rejoined and would also be allowable. If nucleic acid claim 44 is rewritten as an independent claim and limited to the scope of the elected nucleic acid, claims 44, 45, 47-50 could also be rejoined and would be allowable.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

6/26/04


MARY E. MOSHER
PRIMARY EXAMINER
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